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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
AT SAN FRANCISCO

CENTER FOR ENVIRONMENTAL HEALTH, CAPE FEAR RIVER WATCH, CLEAN CAPE FEAR, DEMOCRACY GREEN, THE NC BLACK ALLIANCE, and TOXIC FREE NC Plaintiffs, vs. JANE NISHIDA, as Acting Administrator of the United States Environmental Protection Agency, and the UNITED STATES ENVIRONMENTAL PROTECTION AGENCY . Defendants.	Civ. No. 21-cv-1535 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiffs, Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, The NC Black Alliance, and Toxic Free NC ("Plaintiffs"), as and for their Complaint, allege as follows against Defendants Jane Nishida, as Acting Administrator of the Environmental Protection Agency ("EPA"), and the EPA:

INTRODUCTORY STATEMENT

1. Plaintiffs are nonprofit public health and environmental justice organizations, based in Oakland, California and Eastern North Carolina, concerned about the extensive environmental contamination caused by Per- and Polyfluoroalkyl Substances ("PFAS") and the absence of scientific data on the impacts of this contamination on the health of at risk communities. On October 14, 2020, plaintiffs petitioned defendant Environmental Protection Agency ("EPA") under Section 21 of the Toxic Substances Control Act ("TSCA") to require health and environmental effects testing on 54 PFAS manufactured by The Chemours Company ("Chemours") at its chemical production facility in Fayetteville, North Carolina, downstream of the communities that plaintiffs represent. The petition sought issuance of a rule or order under section 4 of TSCA compelling Chemours to fund and carry out this testing under the direction of a panel of independent scientists. Although the petition demonstrated that the 54 PFAS meet the criteria for testing in section 4(a) of TSCA, defendant EPA denied the petition on January 7, 2021.

2. PFAS have raised significant concern in the US and globally because of their persistence and potential to bio-accumulate, widespread presence in living organisms, products, and the environment, and demonstrated adverse health effects at low doses. In the last few years, several PFAS have been identified in drinking water sources serving nearly 300,000 people in the Cape Fear watershed, in human blood and in environmental media, including air emissions, surface water, sediment, stormwater, groundwater and locally grown produce. This contamination has been linked to the Chemours facility in Fayetteville, which discharges into the Cape Fear River.

3. This action seeks judicial review of the petition denial as authorized in section 21(b)(4)(A of TSCA and the Administrative Procedure Act ("APA"). Plaintiffs ask the Court to compel defendants to initiate a proceeding under section 4(a) of TSCA to issue a rule or order requiring Chemours to fund the studies identified in the petition. The Court should grant this relief because, as plaintiffs demonstrated in their petition and will demonstrate to the Court by a preponderance of evidence, the 54 PFAS meet the standard

for judicial intervention in section 21(b)((4)(B)(i) of TSCA because (1) available information is "insufficient to permit a reasoned evaluation of the[ir] health and environmental effects" and (2) the 54 PFAS "may present an unreasonable risk to health or the environment."

JURISDICTION AND VENUE

4. This action is brought under section 21(b)(4)(A) of TSCA, 15 U.S.C. § 2620, which provides that, upon the denial of a petition under section 21(a), the petitioner "may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition." Such an action must be filed within 60 days of the denial of the petition.

5. This action is also filed under section 706 of the APA, 5 U.S.C. § 706, under which a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

6. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 and 15 U.S.C. §2620(b)(4).

7. The Court has the authority to grant the requested declaratory and injunctive relief under 28 U.S.C. §§ 2201-2202 and 15 U.S.C. §2620(b)(4).

8. Venue is proper in the Northern District of California pursuant to 28 U. S.C. § 1391(e)(1)(C) and 15 U.S.C. §2620(b)(4) because plaintiff Center for Environmental Health resides in the District.

PARTIES

9. Plaintiff Center for Environmental Health ("CEH") is a non-profit organization working to protect children and families from harmful chemicals in air, food, water and in everyday products. Its vision and mission are a world where everyone lives, works, learns and plays in a healthy environment. CEH protects people from toxic chemicals by working with communities, businesses, and the government to demand and support business practices that are safe for human health and the environment. CEH is headquartered in Oakland, California, but members of its staff work in North Carolina and partner closely with locally-

based organizations to address concerns relating to PFAS and other chemicals that threaten the health of North Carolinians.

10. Plaintiff Cape Fear River Watch ("CFRW") is a grassroots environmental nonprofit based in Wilmington, North Carolina whose mission is to protect and improve the water quality of the Cape Fear River Basin for all people through education, advocacy and action. Since its founding, over 25 years ago, it has worked on a wide variety of water quality issues – educating and organizing the community to take action, partnering with researchers, influencing decision makers, and holding polluters accountable. Since learning of the nearly four decades of PFAS contamination of the Cape Fear River, the drinking water supply for nearly 300,000 people, and a vital ecological and economical resource to the region, Cape Fear River Watch, in partnership with academia and the Southern Environmental Law Center, has worked to stop the source of pollution, understand and explain the impacts to human health and the ecosystem, and ensure that those responsible are held accountable.

11. Plaintiff Clean Cape Fear ("CCF") is an all-volunteer, grassroots community group based in the Wilmington, NC area. Its members include educators, environmentalists, doctors, faith leaders, scientists, veterans, and concerned residents all working together to hold Chemours/DuPont accountable for decades of pollution. CFF was formed shortly after learning that toxic chemicals linked to cancer and other serious health problems were detected in finished tap water as a result of Chemours' discharges to the Case Fear River. These discharges and other environmental releases from the facility impact five counties with nearly300,000 residents drinking contaminated tap water downstream from the facility and over 3,500+ well owners with contaminated groundwater near the Fayetteville, NC area.

12. Plaintiff Democracy Green ("DG") is an organization created and run by native North Carolinians-of-color to address the systemic impacts burdening our most climate impacted and disenfranchised communities across North Carolina. DG works in partnership with communities, groups and organizations across the historic U.S. South, in addition to areas hailing the descendants of U.S. chattel slavery and Indigenous sovereign nations. Communities represented by DG have seen the horrific damage caused by

PFAS to North Carolinians and DG cannot stand idly by while the corporations responsible are not held accountable. Democracy Green stands against corporate polluters and the harmful impact of their pollutants and chemicals on frontline communities and low-wealth populations.

13. Plaintiff The NC Black Alliance ("NCBA") is working toward state-level systemic change by strengthening the network of elected officials representing communities of color throughout the state and collaborating with progressive, grassroots networks on intersecting issues. NCBA believes that the communities impacted by climate disasters also face the direct impact of health disparities created by exposure to dangerous chemicals, such PFAS. It is NCBA's conviction that all people have the right to clean air, clean water, access to health care, and a thriving economy.

14. Plaintiff Toxic Free NC ("TFNC") advances environmental health and justice in North Carolina by advocating for safe alternatives to harmful pesticides and chemicals. Founded in 1986, the organization has played a leading role in state-wide pesticide reform and has contributed to national efforts strengthening regulatory protections to protect vulnerable communities and the environment from petrochemical pollution. TFNC believes that PFAS contamination is at the nexus of clean water concerns in North Carolina and that, while high levels of PFAS have been detected in drinking water across the state, the full health impact on the exposed residents of North Carolina is still unknown. Together with other organizations in North Carolina, TFNC advocates for regulatory solutions to prevent further PFAS discharges into our environment and cleanup the PFAS already present. TFNC represents thousands of North Carolina residents whose drinking water has been contaminated and are deeply concerned about the consequences for their health.

15. Defendant Jane Nishida, named in her official capacity as Acting Administrator of EPA, has authority for the implementation of TSCA and is responsible for assuring that the Agency exercises its responsibilities under TSCA in compliance with the law.

16. Defendant EPA is an agency of the United States Executive Branch and, under the direction of Acting Administrator Nishida, is charged with implementing the provisions of TSCA, including by responding to citizens' petitions under section 21.

STATUTORY BACKGROUND

17. TSCA was enacted in 1976 to create a national program for assessing and managing the risks of chemicals to human health and the environment. The need for this comprehensive framework for managing chemical risks was described as follows in the Senate Report on the original law:

> As the industry has grown, we have become literally surrounded by a man-made chemical environment. We utilize chemicals in a majority of our daily activities. We continually wear, wash with, inhale, and ingest a multitude of chemical substances. Many of these chemicals are essential to protect, prolong, and enhance our lives. Yet, too frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers.

Senate Rept. No. 94-698, 94th Cong. 2d Sess. (1976) at 3.

18. Among the goals stated in TSCA section 2(b), 15 U.S.C. §2601(b), is that "adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of this information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."

19. This policy is embodied in section 4 of TSCA, which provides EPA with broad authority to require industry to test its chemicals to determine their risks to human health and the environment. Recognizing the need for more testing to support chemical risk determinations, the 2016 TSCA amendments streamline section 4 by authorizing EPA to issue orders in addition to rules requiring development of data.

20. Section 4(a)(1)(A)(i) authorizes EPA to require testing where it determines that –

> the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, *may present an unreasonable risk of injury to health or the environment* (emphasis added).

21. In *Chemical Manufacturers Association v. U.S. Environmental Protection Agency*, 859 F.2d 977 (1988), the D.C. Circuit concluded that "[b]oth the wording and structure of TSCA reveal that Congress

did not expect that EPA would have to document to a certainty the existence of an 'unreasonable risk' before it could require testing." It added that TSCA's legislative history demonstrates that "the word 'may' in section 4 was intended to focus the Agency's attention on chemical substances 'about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine the effects of the substance or mixture on health or the environment.'"

22. The D.C. Circuit acknowledged that "Congress did not intend to authorize EPA to issue test rules on the basis of mere hunches" but stressed that EPA need not demonstrate that exposure or toxicity is "probable." Instead, EPA may "rely on inferences in issuing a section 4 test rule, so long as all the evidence . . . indicates a more-than-theoretical probability of exposure." Inferences can also support findings of potential toxicity; this can include toxicity data on chemical analogs since "Congress explicitly contemplated that EPA would base test rules on comparisons among structurally similar chemicals."

23. In addition to a "may present" finding, section 4(a)(1)(A)(i) directs EPA to make two further determinations before requiring testing: (1) there is "insufficient information and experience" with which the chemical's effects on health and the environment "can reasonably be determined or predicted"; and (2) testing is "necessary to develop such information." The first determination will be justified whenever data either do not exist or are inadequate to support scientifically supportable conclusions about the chemical's adverse effects. The second determination will be warranted where EPA concludes that the testing to be required is the only way to obtain sufficient information about these effects and that such information cannot be derived from other sources.

24. Once EPA makes these findings, it must require that testing be conducted "to develop information with respect to the health and environmental effects for which there is an insufficiency of information and experience" and which are "relevant to a determination" whether the substance "does or does not present an unreasonable risk to health and the environment."

25. Under section 4(b)(2)(A), a broad range of studies may be required under test rules or orders. These may include studies to determine "carcinogenesis, mutagenesis, teratogenesis, behavioral disorders,

cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment." Studies to be conducted may include "epidemiologic studies, serial or tiered testing, in vitro tests, and whole animal tests." The rule or order can also require development of information "for the assessment of exposure or exposure potential to humans or the environment."

26. Under section 4(b)(3), testing rules or orders must place responsibility for developing the required data on the entities who manufacture and/or process the chemical to be tested. Section 4(b)(1) provides that the rule or order must prescribe the "protocols and methodologies" for conducting testing and procedures and deadlines for submitting interim and final test results.

27. These requirements are enforceable under TSCA and non-compliance may give rise to civil and criminal penalties under section 16 and specific enforcement under section 17.

28. Testing under TSCA section 4 can be required on chemicals produced for intentional use or as byproducts during a commercial chemical manufacturing operation. EPA defines "byproduct" under TSCA as "any chemical substance or mixture produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture." 40 C.F.R. § 712.3(a).

29. Since TSCA's inception, section 21 of the law has contained a petition process by which citizens can seek to compel action by EPA under different provisions of the law. 15 U.S.C. § 2620. The D.C. Circuit has recognized "TSCA's unusually powerful citizen-petition procedures." *Trumpeter Swan Society v EPA*, 774 F.3d 1037, 1939 (D.C, Cir. 2014). EPA is required to respond to the petition within 90 days. If EPA denies the petition or fails to act within 90 days, Section 21 empowers the petitioner to file a civil action in federal district court to "compel the [EPA] Administrator to initiate a rulemaking proceeding as requested in the petition." 15 U.S.C. §2620(b)(4)(A).

30. As amended in 2016, section 21(a) authorizes citizens to petition for, *inter alia*, issuance of a rule or order under Section 4 requiring manufacturers and processors to conduct testing on chemical substances and mixtures. *Id.* § 2620(a). Under Section 21(b)(4)(B), where the petition sought issuance of a rule or

order under section 4, "the petitioner shall be provided an opportunity to have such petition considered by the court in a *de novo* proceeding." 15 U.S.C. § 2620(b)(4)(B).

31. For petitions seeking issuance of rules or orders under section 4, Section 21(b)(4)(B)(i) directs the district court to "order the Administrator to initiate the action requested by the petitioner" if it "demonstrates to the satisfaction of the court by a preponderance of the evidence" that "(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and (II) in the absence of such information, the substance may present an unreasonable risk to health or the environment . . . " 15. U.S.C. §2620(b)(4)(B)(i))I)-(II).

32. Section 26(c)(1) of TSCA authorizes EPA to treat a group of chemical substances as a "category" under section 4 and other TSCA provisions. 15 U.S.C § 2625(c)(1). If the Agency designates chemicals as a "category," testing or other requirements prescribed by EPA would apply to each substance in the category. Under section 26(c)(2), "category" treatment is warranted if chemicals are "similar in molecular structure, in physical, chemical or biological properties, or in mode of entrance into the human body or into the environment" or "in some other way are suitable for classification as such for purposes of this Act."

RISKS OF PFAS TO HUMAN HEALTH AND THE ENVIRONMENT

33. Plaintiffs' October 14, 2020 petition provides considerable background information on PFAS. Highlights are summarized in the paragraphs below.

34. PFAS have a unique set of properties with an unusual ability to cause serious and widespread harm to public health and the environment. A defining feature of PFAS is their carbon-fluorine bonds, which impart high thermal stability and resistance to degradation. Because of their pronounced ability to repel oil and water, PFAS have been used in a variety of industries in the US and around the globe.

35. The EPA Action Plan for PFAS identifies numerous human exposure pathways for these chemicals,

including:[1]

- Drinking water from public water and private water systems, typically localized and associated with a release from a specific facility (e.g., manufacturer, processor, landfill, wastewater treatment, or facilities using PFAS-containing firefighting foams);
- Consumption of plants and meat from animals, including fish that have accumulated PFAS;
- Consumption of food that came into contact with PFAS-containing products (e.g., some microwaveable popcorn bags and grease-resistant papers);
- Use of, living with, or otherwise being exposed to commercial household products and indoor dust containing PFAS, including stain- and water-repellent textiles (including carpet, clothing and footwear), nonstick products (e.g., cookware), polishes, waxes, paints, and cleaning products;
- Employment in a workplace that produces or uses PFAS, including chemical production facilities or utilizing industries (e.g., chromium electroplating, electronics manufacturing, or oil recovery); and
- In utero fetal exposure and early childhood exposure via breastmilk from mothers exposed to PFAS.

36. PFAS are often called "forever" chemicals because they do not break down or degrade over time and therefore are highly persistent. Thus, they build up in the natural environment and in biological systems if they are bioaccumulative. These characteristics, combined with the high mobility of many PFAS, have resulted in their widespread distribution and pervasive presence both in environmental media and in people and wildlife around the globe, including many remote locations. Thus, PFAS have been detected in the blood of workers and the general population, with 99 percent of those sampled showing detectable levels of these compounds.

37. This PFAS body burden is a function of multiple exposure pathways, including air emissions, food and water consumption, consumer products like carpet or clothing and house dust. Because of their resistance to degradation, there is no known safe method of disposal of PFAS that would prevent build-up in the environment at the end of their useful lives.

38. In addition to their persistence, PFAS have high mobility, especially in water. Their high water solubility and environmental persistence together make PFAS a ubiquitous pollutant of surface and

[1] EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan, February 2019.

groundwater. As a result, PFAS-contaminated drinking water is a widespread threat across the US; a growing number of drinking water suppliers have detected PFAS in source water or tap water, raising concerns about drinking water safety and resulting in use of costly treatment systems in numerous communities across the country.

39. Animal studies demonstrate that PFAS are linked to many serious health effects, including cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immunotoxicity, often at low doses. Human studies of populations with elevated blood levels of PFAS have shown associations with a variety of health conditions, including kidney and testicular cancer, elevated cholesterol, liver disease, decreased fertility, thyroid problems and changes in hormone levels and immune systems. Moreover, concurrent exposure to multiple PFAS may have additive or synergistic effects.

40. To date, EPA has failed to use its testing authorities under TSCA section 4 to fill the extensive data-gaps on PFAS.

CONTAMINATION OF THE CAPE FEAR RIVER BASIN BY THE CHEMOURS FACILITY

41. Plaintiffs' petition also described in detail the operation of the Chemours' facility in Fayetteville, North Carolina and the PFAS contamination it has created in the Cape Fear River basin. Key highlights are summarized in the following paragraphs.

42. The Chemours plant is located on a 2,150-acre site in a rural area south of Fayetteville, adjacent to the west bank of the Cape Fear River. The river continues for over 110 km to the City of Wilmington and then broadens into an estuary that ultimately flows into the Atlantic Ocean. Residents of Wilmington and other population centers downstream from the facility use the river as a source of drinking water. .

43. The facility was built and operated by DuPont and started producing fluoropolymers in 1971. In 2015, DuPont spun off its performance chemicals business to Chemours, a newly created company which then acquired the Fayetteville plant and other former DuPont facilities.

44. The plant is a major producer and user of PFAS. Its PFAS-based product lines are

Fluoromonomers, Fluorinated Vinyl Ethers and Nafion® Polymers, which are used as membranes in fuel cells and chlorine production. The mix of precursors, byproducts, degradation products and commercial substances associated with these product lines is complex and not well-understood but likely involves hundreds if not thousands of individual PFAS, many of which have chemical structures that are as yet unidentified.

45. A major source of concern has been Chemours' production of "GenX" compounds. These chemicals have been produced as byproducts at the Fayetteville since the early 1980s. They were recently commercialized as a replacement for perfluorooctanoic acid (PFOA), a surfactant in the polymerization of fluoropolymers that was phased out in 2015 in response to health and environmental concerns.

46. During monitoring by Strynar et al. and Sun et al., GenX and nine other PFAS were identified in the Cape Fear River and drinking water downstream of the Fayetteville plant.[2] In further sampling of the river downstream of the plant, McCord et al. (2019) found 37 unique PFAS molecules.[3] Several of these compounds were also detected in the blood of residents of the Cape Fear region, confirming human exposure.[4] Sampling in the Cape fear River indicated that total PFAS concentrations (all substances combined) were 130,000 parts per trillion (ppt).[5] Sampling by water utilities subsequently identified numerous PFAS linked to Chemours' operations in drinking water intakes.

47. As concern increased about surface water and drinking water contamination, monitoring of other environmental media for the presence of PFAS produced at the Fayetteville plant was initiated. As

[2] Hopkins, Z. R., Sun, M., DeWitt, J. C. & Knappe, D. R. U. Recently Detected Drinking Water Contaminants: GenX and Other Per- and Polyfluoroalkyl Ether Acids. *Journal AWWA* **110**, 13-28, doi:10.1002/awwa.1073 (2018).

[3] McCord, J. & Strynar, M. Identification of Per- and Polyfluoroalkyl Substances in the Cape Fear River by High Resolution Mass Spectrometry and Nontargeted Screening. *Environmental Science & Technology* **53**, 4717-4727, doi:10.1021/acs.est.8b06017 (2019).

[4] Kotlarz, N. *et al.* Measurement of Novel, Drinking Water-Associated PFAS in Blood from Adults and Children in Wilmington, North Carolina. *Environmental Health Perspectives* **128**, 077005, doi:doi:10.1289/EHP6837 (2020).

[5] Zhang, C., Hopkins, Z. R., McCord, J., Strynar, M. J. & Knappe, D. R. U. Fate of Per- and Polyfluoroalkyl Ether Acids in the Total Oxidizable Precursor Assay and Implications for the Analysis of Impacted Water. *Environ Sci Technol Lett* **6**, 662-668, i:10.1021/acs.estlett.9b00525 (2019).

determined in Chemours' compliance testing under a North Carolina consent order, several additional PFAS associated with the Fayetteville Works facility have been detected in private wells, wastewater, stormwater, sediment, groundwater, soil, air emissions, and local produce, including a large number of compounds of uncertain chemical composition.

48. The 2019 consent order between Chemours and the North Carolina Department of Environmental Quality (DEQ) requires controls on wastewater discharges and air emissions of PFAS, directs Chemours to identify constituents of wastewater and process streams and to conduct environmental monitoring, provides for groundwater remediation, and requires health and environmental effects testing of five PFAS. Sampling of drinking water systems and private wells since the order was issued documents the continuing presence of GenX and several other PFAS.

PLAINTIFFS' PETITION FOR A TEST RULE OR ORDER UNDER TSCA SECTION 21

49. Plaintiffs' petition identified 54 PFAS linked to the Chemours facility that warrant health and environmental effects testing. Petitioners selected these 54 PFAS based on evidence of known or anticipated human exposure as demonstrated by available data on their presence in human sera, drinking water, surface water, air emissions, rainwater, private wells, groundwater and produce. The petition maintained that the 54 PFAS meet TSCA criteria for testing because (1) data on their effects are insufficient or unavailable and (2) they may present unreasonable risks by virtue of the combination of potential toxicity and exposure.

50. The 54 PFAS were divided into Tier 1 substances (for which there is known human exposure based on detection in blood, food or drinking water) and Tier 2 substances (for which human exposure is probable based on detection in environmental media). The detailed justification for assigning substances to these Tiers is provided in Attachment 2 to the petition, the Chemours PFAS Master Testing List.

51. The petition maintained that, since EPA and other authorities have recognized that all PFAS have the potential for causing the adverse health and environmental effects linked to well-characterized substances in the class, there is a strong basis to conclude that the 54 PFAS "may present an unreasonable

risk of injury" under TSCA section 4(a)(1)(A). According to the petition. this potential risk is magnified by the co-occurrence of multiple PFAS in drinking and surface water, other environmental media and the blood of humans and wildlife in the Cape Fear watershed. Where exposure is to multiple PFAS simultaneously, the petition emphasized, their toxic effects may be additive or synergistic, resulting in greater overall risk than exposure to any individual PFAS alone.

52. The petition also maintained that the "sufficiency" of available information on the 54 PFAS should be determined by comparing available data with the known adverse effects of other PFAS. According to the petition, if a scientifically sound assessment of each of the 54 chemicals for these critical toxic endpoints cannot be conducted because of the lack of data, available information on these substances should be deemed "insufficient" under TSCA section 4(a).

53. The petition then showed that the 54 substances lack any health and ecological effects data or the available studies are limited and incomplete and do not provide an adequate basis for hazard and risk assessment. Key data gaps include measurement of physical-chemical properties, methods of analysis, assessment of partitioning, bioaccumulation, and degradation, pharmacokinetics, and toxicity, especially for the endpoints commonly observed for the better studied PFAS, such as liver toxicity, and effects on the immune system, lipid metabolism, kidney, thyroid, development, reproduction, and cancer. In addition, despite their widespread detection in environmental media, ecotoxicity data are generally lacking.

54. Based on its showings of potential unreasonable risk and insufficiency of data, the petition proposed the following testing program:

Experimental Animal Studies

- Compounds in both Tiers would undergo 28-day repeated dose rodent toxicology studies coupled with reproductive and developmental toxicity screening assays, examining critical PFAS endpoints including hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity.

- These studies would also be conducted on three mixtures of PFAS representative of the groups of substances to which residents have been exposed through drinking water, human sera and other pathways.

- Multigeneration or extended one-generation and 2-year rodent carcinogenicity studies would be conducted on the 14 Tier 1 substances in recognition of the evidence of direct and substantial human exposure and the concerns for these endpoints demonstrated by other PFAS.

- Most studies would be carried out in two species (mice and rats) and by oral routes of administration, except inhalation would be used for volatile chemicals.

- Toxicokinetic studies would be conducted to characterize relationships between serum concentrations and dermal, oral and inhalation exposures in the test species, and to evaluate biological half-life and potential for bioaccumulation.

- Testing requirements would be based on EPA and OECD guidelines, with appropriate adjustments to reflect sensitive endpoints that have been reported for PFOA, PFOS, and GenX.

Human Studies

- A human health study for the Cape Fear watershed would be conducted using a similar study design to that used for the Parkersburg, WV PFOA (C8) study. The goal of the study would be to determine the relationship between exposure to the mixtures of PFAS that characterize current and historical exposure in the Cape Fear watershed and health outcomes among exposed populations.

- Testing would also be performed to determine human half-lives of the listed chemicals through longitudinal biomonitoring and exposure estimation in workers.

Ecological Effects/Fate and Transport and Physical-Chemical Properties Studies

- Testing would include ecological effects studies, similar to studies conducted on GenX.

- EPA would require development of analytical standards where not currently available, physical-chemical properties tests, and fate and transport studies in order to identify and predict exposures.

55. The petition proposed that, to maximize the credibility and objectivity of the data and key findings, EPA contract with the National Academy of Sciences (NAS) to form an independent expert science panel with responsibility for overseeing all aspects of the testing program. The public and Chemours would have the opportunity to submit nominations for membership on the panel.

EPA'S DENIAL OF PLAINTIFFS' PETITION

56. The January 7, 2021 petition denial affirmed EPA's "high concern" about PFAS and did not dispute that all PFAS are of concern for serious health effects based on the properties of the class. Nor did EPA deny that most of the 54 PFAS have been detected in the environment, resulting in exposure by North Carolina residents and putting them at risk of harm.

57. The bulk of the petition denial (pp. 8-18) consists of a lengthy summary of the EPA PFAS Action Plan and a detailed list of the various PFAS-related measures EPA has taken under the Plan and other programs. This list of EPA accomplishments is irrelevant to the petition. These EPA actions do not speak to whether the 54 PFAS in the petition meet the criteria for testing in section 4 of TSCA and provide no basis for denying the petition.

58. The petition denial also asserts (p. 19) that "the petitioners have not provided the facts necessary for the Agency to determine for each of the 54 PFAS that existing information and experience are insufficient and testing of such substance or mixture with respect to such effects is necessary to develop such information."

59. However, before filing the petition, plaintiffs reviewed the available data for the 54 PFAS. As the petition explains, some testing has been conducted or is underway on a small number of compounds but it fails to provide necessary data for all-endpoints and most of the 54 PFAS have no health effects data at all.

60. In addition, EPA and many other expert bodies agree that there are fundamental data gaps for nearly all PFAS. As underscored in EPA's PFAS Action Plan, "[t]here are many PFAS of potential concern to the public that may be found in the environment. Most of these PFAS lack sufficient toxicity data to inform our understanding of the potential for adverse human or ecological effects."

61. The petition denial (pp. 23-24) also "finds that the petitioners failed to address ongoing testing and data collection for some of the 54 PFAS, thereby failing to set forth facts that are necessary to establish there is a need for the testing sought in the petition. This research may provide information that overlaps with testing the petitioners requested, which would render the information unnecessary under TSCA section 4(a)(1)(A)(i)(III)."

62. However, nearly all the ongoing research cited by EPA consists of *in vitro* assays, including high-throughput testing conducted by the EPA Office of Research and Development (ORD) to determine various markers of bioactivity that might signal the potential for *in vivo* effects. The health effects testing proposed in the petition consists of *in vivo* animal studies, epidemiological research and limited monitoring of

workers. No *in vitro* assays are included. Non-animal test methods (New Approach Methods or NAMs) cannot at this time provide a scientifically sufficient understanding of the health and environmental effects of PFAS.

PETITIONERS' REQUEST FOR RECONSIDERATION

63. On March 4, 2021, plaintiffs submitted to defendant EPA a request to reconsider and grant their October 14, 2020 petition. The request provided a point-by-point rebuttal to the grounds for Agency's January 7, 2021 petition denial.

64. To eliminate any possible doubt about the insufficiency of available data for the 54 PFAS, the reconsideration request provided the results of a systematic and comprehensive literature search conducted by petitioners' scientific consultants on these substances. This search included EPA's ChemView and CompTox data-bases as well as Pub-Med and ECHA files. The search showed that the 54 PFAS lack most or all of the studies proposed in plaintiffs' petition.

FIRST CLAIM FOR RELIEF

65. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 64 as if fully set forth herein.

66. TSCA section 21(b)(4)(A) provides a right to judicial review in an appropriate district court within 60 days following denial of a petition to issue a rule or order requiring testing under TSCA section 4.

67. On October 14, 2020, plaintiffs petitioned defendant EPA under Section 21(a) of TSCA to require health and environmental effects testing on 54 PFAS manufactured by Chemours at its chemical production facility in Fayetteville, North Carolina, downstream of the communities that plaintiffs represent. The petition sought issuance of a rule or order under section 4 of TSCA compelling Chemours to fund and carry out this testing under the direction of a panel of independent scientists.

68. EPA denied the petition on January 7, 2021.

69. Following the denial of a petition seeking the issuance of a rule or order under TSCA section 4, section 21 provides that "the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding." 15 U.S.C. §2620(b)(4)(B).

70. Section 21(b)(4)(B)(i) provides that, where the petition seeks issuance of a rule or order under section 4, the district court shall "order the Administrator to initiate the action requested by the petitioner" if it "demonstrates to the satisfaction of the court by a preponderance of the evidence" that "(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and (II) in the absence of such information, the substance may present an unreasonable risk to health or the environment . . . " 15. U.S.C. §2620(b)(4)(B)(i))I)-(II).

71. The preponderance of the evidence to be presented by plaintiffs demonstrates that the 54 PFAS proposed for testing in their petition meet these standards for ordering EPA to issue a test rule or order under section 4 TSCA.

72. The Court should thus direct EPA to initiate a proceeding for the issuance of a rule or order requiring Chemours to carry out the studies on the 54 PFAS specified in plaintiffs' petition.

SECOND CLAIM FOR RELIEF

73. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 64 as if fully set forth herein.

74. Under section 706 of the APA, 5 U.S.C. § 706, a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

75. Denials of petitions under TSCA section 21 are reviewable under these APA provisions as well as under the *de novo* review provisions in section 21(b)(4)(B).

76. Defendants January 7, 2021 denial of plaintiffs' petition was arbitrary and capricious, an abuse of discretion and not in accordance with law.

77. The petition denial should be declared unlawful under the APA judicial review provisions.

78. Under section 21(b)(4), if denial of a petition is set aside under the APA, the Court may order EPA "to compel the Administrator to initiate a rulemaking proceeding as requested in the petition."

79. The Court should thus direct EPA to initiate a proceeding for the issuance of a rule or order requiring Chemours to carry out the studies on the 54 PFAS specified in plaintiffs' petition.

REQUEST FOR RELIEF

WHEREFORE, plaintiffs respectfully request judgment in their favor and against defendants upon their claims and, further, request that this Honorable Court enter judgment against defendants:

(1) Declaring that plaintiffs have demonstrated by a preponderance of the evidence that, with respect to the 54 PFAS proposed for testing in their petition, "(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and (II) in the absence of such information, the [PFAS]may present an unreasonable risk to health or the environment . . ., " pursuant to 15 U.S.C. § 2620(b)(4)(B)(i);

(2) Declaring that defendants' denial of plaintiffs' petition was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law under 5 U.S.C. § 706;

(3) Ordering defendants to initiate a proceeding for the issuance of a rule or order under TSCA section 4 requiring Chemours to conduct the studies on the 54 PFAS requested in plaintiffs' petition, pursuant to 15 U.S.C. § 2620(b)(4)(B);

(4) Awarding plaintiffs their costs of suit and reasonable fees for attorneys and expert witnesses in this action pursuant to 15 U.S.C. § 2620(b)(4)(C); and

(5) Granting plaintiffs such further and additional relief as the Court may deem just and proper.

Respectfully submitted this 3rd day of March 2021.

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